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PATENT



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

Jerome B. Zeldis, et al.

Confirmation No.: 8455

Application No.: 10/820,397

Group Art Unit: 1612

Filing Date: April 8, 2004

Examiner: Darryl C. Sutton

For: **METHODS OF TREATMENT OF COGNITIVE AND MENOPAUSAL
DISORDERS WITH D-THREO METHYLPHENIDATE**

EXPRESS MAIL LABEL NO: EV 940609165 US
DATE OF DEPOSIT: February 13, 2008

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 CFR § 1.56 and in accordance with 37 CFR §§ 1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 CFR § 1.56(b).

- ☒ In accordance with § 1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified application, within three months of the date of entry into the national stage of the above identified application as set forth in § 1.491, before the mailing date of a first Office Action on the merits of the above-identified application, or before the mailing date of a first Office Action after the filing of request for continued examination under § 1.114, no additional fee is required.

- ☒ Copies of reference numbers 55-102 listed on the attached Form PTO-1449 are enclosed herewith.
- ☒ Copies of reference numbers 11 - 54 on the attached Form PTO 1449 are not required to be submitted pursuant to 37 CFR § 1.98(a)(2)(ii).
- ☐ Copies of references - are not being submitted because they were previously cited by or submitted to the U.S. Patent and Trademark Office in patent application number , filed for which a claim for priority under 35 U.S.C. § 120 has been made in the instant application.
- ☒ The relevance of those listed references which are not in the English language is as follows:
- U.S. Patent No. 4,968,505 is an English language equivalent of FR 2 635 460 (Reference 63), which is not in the English language.
- Applicant does not admit, represent, or acknowledge that reference No. 85 (the Srinivias Thesis) is material, or enabled, or qualifies as prior art or is non-cumulative of the 1992 Srinivas scientific article submitted with the Information Disclosure Statement filed by the Applicant on August 20, 2004.
- Items 90 to 102 are documents from pending litigations that involve U.S. Patent No. 6,635,284, which issued from a divisional of the application that became U.S. Patent No. 5,837,284 (collectively, the “ ‘284 patents”), or that otherwise involve patents possibly relating to subject matter sought by the instant patent application. These litigations correspond to the following case captions:
1. *Celgene Corporation, Novartis Pharmaceuticals Corporation and Novartis Pharma AG v. Teva Pharmaceuticals USA, Inc.*, Civil Action No. 04-4030 (FLW) (consolidated with Civil Action No. 06-6154 (FLW)), District of New Jersey;

information is material. Items 90 to 102 are pleadings that contain or relate to statements by the defendants in the above-referenced litigations concerning the '284 patents, and/or other patents at-issue in those litigations possibly relating to subject matter sought by the instant patent application.

By these submissions, Applicants neither make any admission as to the materiality of the information to patentability of the present application or parent cases, nor agree with the allegations made against the patents-at-issue in the litigations.

The Applicant respectfully requests that the Examiner review the listed items and that they be made of record in the present application.

Please charge any deficiency or credit any overpayment to Deposit Account No. 23-3050. This form is submitted in duplicate.

Date:

February 13, 2008

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2. *Celgene Corporation, Novartis Pharmaceuticals Corporation and Novartis Pharma AG v. Abrika Pharmaceuticals, Inc. and Abrika Pharmaceuticals, LLLP*, Civil Action No. 06-5818 (SDW), District of New Jersey;

3. *Celgene Corporation, Novartis Pharmaceuticals Corporation and Novartis Pharma AG v. Teva Pharmaceuticals USA, Inc.*, Civil Action No. 07-4459 (FLW), District of New Jersey;

4. *Celgene Corporation, Novartis Pharmaceuticals Corporation and Novartis Pharma AG v. KV Pharmaceutical Company*, Civil Action No. 07-4819 (SDW), District of New Jersey;

5. *Celgene Corporation, Novartis Pharmaceuticals Corporation and Novartis Pharma AG v. IntelliPharmaCeutics Corp.*, Civil Action No. 07-4854 (FLW), District of New Jersey; and

6. *Celgene Corporation, Novartis Pharmaceuticals Corporation and Novartis Pharma AG v. Barr Laboratories, Inc. and Barr Pharmaceuticals, Inc.*, Civil Action No. 07-5256 (SDW), District of New Jersey.

Copies of the patents at-issue in each of the above-referenced litigations are attached as exhibits to the complaint corresponding to each litigation. (See Items 90, 93, 96, 98, 99, and 100, respectively.)¹

While the Patent Owner is expressly refraining from making any representation that the subject matter sought by the instant patent application is or has been involved in any litigations, the Patent Owner is filing the instant Information Disclosure Statement to ensure satisfaction of any duty by the Patent Owner to disclose to the PTO the existence of these litigations, including any material information arising therefrom, pursuant to 37 CFR 1.56(b) and/or MPEP §2001.06(c), though the Patent Owner makes no representation that any such

¹ Though not attached as an exhibit to the complaint for Litigation No. 1 above, U.S. Patent No. 5,908,850 (the “‘850 patent”) is also the subject of Litigation No. 1 (i.e., Civil Action No. 04-4030 (FLW)). The ‘850 patent was attached as an exhibit to a prior complaint that was consolidated with the complaint included here, into a single litigation case. The prior complaint that refers to the ‘850 patent as an exhibit was previously disclosed to the PTO as item No. 501 in an IDS filed on November 6, 2006, in the instant patent application.